AUG 1 2013

510(k) SUMMARY

K123571

Date: July 24, 2013

Submitter:

Name:	Cardiomedical GmbH
Address:	Industriestraße 3a D-30855 Langenhagen Germany
Contact Person:	Wolfgang Wiedenbein
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Product:

Trade Name:	Cardio Vision® MICS Aortic Clamps
Common Name:	Vascular Clamp
Classification Name:	Vascular Clamp
Product Code:	DXC
Regulation No:	870.4450

Predicate Device:

- K110148 – Wexler Vascular Clamp Series
- K810162, K832554 – Edwards Fogarty Soft Jaw Clip

Device Description: Cardio Vision® MICS Aortic Clamps are reusable stainless steel vascular clamps provided with DeBakey tooth design. The closure mechanisms permit the surgeon to adjust the amount of tension applied to the vessel. The length and design of the clamps can be important to keep the devices out of the field of vision of the operative site. Three basic models are available to accommodate the individual needs of the surgeon and the procedure based on the anatomy of the site.

- Standard Clamp – Ring-handled clamp with ratchet closure
- 2nd Generation Clamp – Handleless clamp with manual screw mechanism closure
- Clamp by Glauber – Handleless clamp with screw mechanism closure. The clamp is positioned and removed by means of an applicator and remains wholly within the thorax throughout the duration of the procedure.

The device is provided non-sterile for steam sterilization by the user.

Indications for Use: Cardio Vision® MICS Aortic Clamps are indicated for use for temporary or partial occlusion of blood vessels during surgical procedures.

Technological Characteristics The device has similar technological and performance characteristics as the predicate devices, as shown by the following summary table:

Manufacturer	Cardiomedical	Wexler K110148	American Edwards Laboratories K810162, K832554
Indications for Use	Cardio Vision® MICS Aortic Clamps are indicated for use for temporary or partial occlusion of blood vessels during surgical procedures.	The Wexler Vascular Clamp Series is indicated for use for temporary or partial occlusion of blood vessels during surgical procedures.	The Fogarty Softjaw Spring Clips and Handleless Clamps and Fogarty-Hydragrip Surgical Clamp Insert Sets are intended for atraumatic vessel occlusion for distinct vessel conditions and procedures.
Design	Ring-handled clamps with ratchet. Handleless clamps with screw closure mechanism adjusted manually or by means of an applicator.	Ring-handled clamps with ratchet.	Handleless clips and clamps or ring-handle surgical clamp insert sets with flexible shaft, provided with positioning device.
Principle of Operation	Clamp jaws are applied to the vessel. The amount of tension applied to the vessel for occlusion or partial occlusion is adjusted by means of the ratchet or screw closure mechanism.	Clamp jaws are applied to the vessel. The amount of tension applied to the vessel for occlusion or partial occlusion is adjusted by means of the ratchet closure mechanism.	Clamp jaws are applied to vessel. The amount of tension applied to the vessel for occlusion or partial occlusion is determined by the spring or adjusted by means of the ratchet closure.
Material	Stainless Steel	Stainless Steel	
Sterility	Non-sterile	Non-sterile	
Reusable	Yes	Yes	

Testing: Bench and animal testing was performed to assess clamp force and aortic tissue damage. Comparison testing included Wexler Vascular Clamp Series (K110148), Transthoracic Aortic Clamp (K982365), and Cygnet Clamp (K010727).

Conclusion: The information provided in this 510(k) submission demonstrates that subject device Cardio Vision® MICS Aortic Clamps is substantially equivalent to the predicate devices with respect to intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 1, 2013

Cardiomedical GMBH
C/O Business Support International
Amstel 320-1
Amsterdam, Noord-Holland
Netherlands, 1017AP
ATTN: Angelika Scherp

Re: K123571
Trade/Device Name: Cardio Vision MICS Aortic Clamps
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: June 6, 2013
Received: June 7, 2013

Dear Ms. Scherp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123571

Device Name: CARDIO VISION® MICS AORTIC CLAMPS

Indications for Use: Cardio Vision® MICS Aortic Clamps are indicated for use for temporary or partial occlusion of blood vessels during surgical procedures.

Prescription Use __X__ AND/OR **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)